

U.S. Department of Transportation

Research and Special Programs Administration

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Mr. Jeffrey J. Joaquim
Environmental Health and Safety
Manager,
Cytyc Corporation
85 Swanson Rd
Boxborough, MA 01719

Ref. No. 02-0200

400 Seventh Street, S.W.

Washington, D.C. 20590

Dear Mr. Joaquim:

This is in response to your July 29, 2002 letter regarding the small quantity exception requirements. Specifically, you are interested in the absorbent material requirements contained in \$ 173.4(a)(4) of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180).

Your questions are paraphrased and answered as follows:

- Q1. Does the inside of the outer packaging need to be lined with a cushioning or absorbent material?
- A1. The HMR do not specifically state that the inside of the outer packaging must be lined with either cushioning or absorbent materials. The inner packagings must be so packed, secured, and cushioned, in a strong outside packaging, to prevent their breakage or leakage under conditions normally incident to transportation. In the event of leakage from a receptacle, the absorbent material must be capable of absorbing the entire content of that receptacle.
- Q2. Does the absorbent material need to be capable of absorbing the contents of one receptacle or the entire content of the completed package?
- A2. The absorbent must be capable of absorbing the entire content of all inner receptacles used as packaging for the hazardous materials (see § 173.4(a)(4)(ii)).



173.4

- Q3. May the trays, each containing 25 inner receptacles, be placed in a plastic bag as a means of meeting the absorbent material requirement?
- A3. No, you cannot meet the absorbent material requirement by using an impermeable barrier within the package to preclude leakage from the package.
- Q4. Is there an external pressure where it would be acceptable for the absorbed liquid to be released from the absorbent material?

A4. No specific external pressure is provided in the HMR.

However, the retained liquid must remain absorbed under conditions normally incident to transportation.

I hope this information is helpful. If you have further questions, please do not hesitate to contact this office.

Sincerely,

John A. Gale

Transportation Regulations Specialist Office of Hazardous Materials Standards July 25, 2002

Mr. Edward T. Mazzullo Director, Office of Hazardous Materials Standards U.S. DOT/RSPA (DHM-10) 400 7th Street S.W. Washington, D.C. 20590-0001

Re: 49 CFR 173.4 Small Quantity Exceptions

Dear Mr. Mazzullo:

Cytyc Corporation, based in Boxborough, Massachusetts (USA), designs, develops, manufactures, and markets sample preparation systems for medical diagnostics. An alcohol based preservative solution is used to preservative and transport the cytology. This solution has a flash point of 80°F. The volume of solution in each vial is 20 ml. A safety seal secures the caps to each vial. The vials are constructed of approximately 0.8 mm thick plastic and have a capacity of approximately 60 ml. The plastic vials and the solution are chemically compatible. The vials are currently packaged for shipment as follows: 25-vials are nested in plastic egg crate like trays. The 25-pack trays are individually shrunk wrapped. 10-trays are placed in a cushioned cardboard box that meets the Packing Group II requirements.

Cytyc would like to take advantage of the Small Quantity Exceptions indicated in 49 CFR 173.4. We need some clarifications to proceed. We understand that the complete packaging will have to be able to pass the Packing Group I drop test regiment, have a statement that reads to the effect that "This package conforms to 49 CFR 173.4" on the exterior of the carton, etc. The questions pertain to the absorbing material. Assume the absorbing material is chemically compatible with the solution.

- Do we need to line the entire carton with absorbing material?
- Does the absorbing material need to be capable of absorbing only 20 ml (the contents of 1-vial), or do we need enough absorbing material to absorb the contents of all the vials (5-liters) in the carton?
- · Can we enclose each shrunk wrapped 25-pack of vials in a sealed plastic bag in place of using absorbing material?
- Since the purpose of the absorbing material is to prevent the captured solution from contaminating the exterior of the carton or escaping into the environment, is there a there a specification as to how much external pressure can be exerted on carton before some of the absorbed or captured liquid is released?

BAH SMall Quantity Exceptions 02-0200 It is our desire to take advantage of § 173.4 in the very near future. Your timely response would be much appreciated.

Sincerely,

Jeffrey J. Joaquim, CIH, CSH, MS Environmental Health and Safety Manager

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